

Docket No.: 03368/100D888-US1

In re application of: Charles E. ROGLER et al.

Art Unit: 1632

Examiner: P. Paras, Jr.

For: **CHRONIC HEPATITIS VIRUS INFECTION AND CLONAL HEPATOCELLULAR CARCINOMA IN MOUSE REPOPULATED LIVERS**

INFORMATION DISCLOSURE STATEMENT

March 19, 2004

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☒ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☐ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months

prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

- ☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449, PTO-892, or form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☒ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☒ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

Serial No. 09/344,189, filed June 24, 1999; and

Serial No. 09/156,892, filed September 18, 1998.

Applicant Identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

Mitchell Beanton

Mitchell Bernstein, Ph.D.

Registration No. 46,550

Agent for Applicant(s)

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FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE

(REV. 7-80)

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 3368/1D888-US1

SERIAL NO: 09/344,189

APPLICANTS: Charles E. ROGLER et al.

FILING DATE: June 24, 1999

U.S. PATENT DOCUMENTS

<u>*EXAMINER INITIALS</u>	<u>DOCUMENT NUMBER</u>	<u>DATE</u>	<u>NAME</u>	<u>CLASS</u>	<u>SUBCLASS</u>	<u>FILING DATE</u>
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FOREIGN PATENT DOCUMENTS

<u>*EXAMINER INITIALS</u>	<u>DOCUMENT NUMBER</u>	<u>DATE</u>	<u>COUNTRY</u>	<u>CLASS</u>	<u>SUBCLASS</u>	<u>TRANSLATION YES NO</u>
1.	WO 94/02601	Feb. 3, 1994	EPO	C12N	15/00	X

OTHER REFERENCES**(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)***EXAMINER
INITIALS

EXAMINER: _____ DATE CONSIDERED: _____

*EXAMINER:

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

LIST OF REFERENCES CITED BY APPLICANT

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DOCKET NO.: 0342/1D888US1
APPLICANT: Charles E. ROGLER
FILING DATE: 06/24/99

SERIAL NO: 09/344,189

U.S. PATENT DOCUMENTS

*EXAMINER INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS

*EXAMINER INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
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OTHER REFERENCES**(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)**

*EXAMINER
INITIALS

1. Chisari, F.V. *et al.* (1995) *Annu. Rev. Immunol.* 13:29-60
2. Chisari, F.V. (1996) *Curr Topics Microbiol Immunol* 206:150-173
3. Guidotti, L.G. *et al.* (1994) *Proc. Natl. Acad. Sci. USA* 91:3764-3768
4. Guidotti, L. G. *et al.* (1996) *Immunity* 4:25-36
5. Gupta, S. *et al.* (1996) *Prog Liv Dis* 14:199-222
6. Sandgren, E.P. *et al.* (1991) *Cell* 66:245-256
7. Rhim, J.A. *et al.* (1994) *Science* 263:1149-1152
8. Rhim, J.A., *et al.* (1995) *Proc. Natl. Acad. Sci. USA* 92:4942-4946
9. Roggendorf, M. *et al.* (1995) *Intervirology* 38:100-112
10. Korba, B.E. *et al.* (1989). *J Virol* 63:1360-70

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DOCKET NO.: 0342/1D888US1
APPLICANT: Charles E. ROGLER
FILING DATE: 06/24/99

SERIAL NO: 09/344,189

11. Tennant, B.C. *et al.* (1994) in *The Liver. Biology and Pathobiology*, eds. Arias, I.M., *et al.* (Raven Press, New York) pp 1455-1469
12. Shinkai, Y. *et al.* (1992) *Cell* 68:855-867
13. Overturf, K. *et al.* (1996) *Nature Genetics* 12:266-273
14. Grompe, M. *et al.* (1993) *Genes and Development* 7:2298-2307
15. Overturf, K. *et al.* (1997) *Am. J. Path.* 151:1273-1280
16. Marie-Jeanne, T. *et al.* (1997) *Hepatology* 25:884-888
17. Petersen, J. *et al.* (Sept. 1997) Abstract No. 041, Molecular Biology of Hepatitis B Viruses, Institut Pasteur
18. Petersen, J. *et al.* (1998) *Proc. Natl. Acad. Sci. USA* 95:310-315
19. Petersen, J. *et al.* (1997) *Hepatology* 26(4), pt. 2, 225A, Abstract # 387

EXAMINER: _____

DATE CONSIDERED: _____

***EXAMINER:**

Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

(D&D Forms/PTO-17)

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Charles E. Rogler
				Art Unit	1632
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	03368/100D888-US3

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	Laconi, E. et al. (1998) American Journal of Pathology, Vol. 153, pp. 319-327	
	CB	Janeway Jr., C. et al. (1997) Immunobiology, 3d., pp. 317-319	
	CC	Overturf, K., et al. (1996) Nature Genetics, Vol. 12, pp. 266-272	
	CD	Mercer, D., et al. (2001) Nature Medicine, Vol. 7, pp. 927-932	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

W:1033 68100d		Date Considered	
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Notice of References Cited

Application/Control No.

09/344,189

Applicant(s)/Patent Under
Reexamination
ROGLER, CHARLES E.

Examiner

Peter Paras, Jr.

Art Unit

1632

Page 1 of 1

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	DOCUMENT SOURCE **	
							APS	OTHER
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NON-PATENT DOCUMENTS

*		DOCUMENT (Including Author, Title Date, Source, and Pertinent Pages)	DOCUMENT SOURCE **	
			APS	OTHER
<input type="checkbox"/>	U	Kuby et al, 1994, Immunology, 2nd edition, Freeman Press, page 26.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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<input type="checkbox"/>	W		<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	X		<input type="checkbox"/>	<input type="checkbox"/>

*A copy of this reference is not being furnished with this Office action. (See Manual of Patent Examining Procedure, Section 707.05(a).)

**APS encompasses any electronic search i.e. text, image, and Commercial Databases.

U.S. Patent and Trademark Office

PTO-892 (Rev. 03-98)

Notice of References Cited

Part of Paper No. 5

Notice of References Cited	Application/Control No. 09/344,189	Applicant(s)/Patent Under Reexamination ROGLER, CHARLES E.	
	Examiner Peter Paras	Art Unit 1632	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification	
	A	US-6,034,297-	09-1997	Vierling	800	9
	B	US-5,583,278-	05-1994	Alt et al.	800	2
	C	US-5,980,886-	03-1997	Kay et al.	424	93.21
	D	US- -				
	E	US- -				
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	I	US- -				
	J	US- -				
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	N	- -					
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	R	- -					
	S	- -					
	T	- -					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)					
	U	WS Robinson, Fundamental Virology, 2nd Ed., "Hepadnaviridae and Their Replication," 1991 Chap. 38, pp. 989-1021.					
	V	FB Hollinger et al., Fields Virology, "Hepatitis A Virus," 3rd. Ed., Chap.24, pp. 735 and 751-752.					
	W	RH Purcell, Fields Virology, "Hepatitis E Virus," 3rd. Ed., Chap. 89, pp. 2831-2836.					
	X	GL Burngardner et al., Immunological Reviews, "Unusual patterns of alloimmunity evoked by allogeneic liver parenchymal cells," 2000, Vol. 174, pp. 260-279.					

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 09/344,189	Applicant(s)/Patent Under Reexamination ROGLER, CHARLES E.	
	Examiner Peter Paras	Art Unit 1632	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US- -			
	B	US- -			
	C	US- -			
	D	US- -			
	E	US- -			
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
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	R	- -				
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	T	- -				

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	M Houghton, Fields Virology, 3rd. Ed., "Hepatitis C Viruses," Chap.32, pp. 1035-1036.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP, § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.